

Preliminary Remarks:

With entry of this amendment, applicants respectfully request the suspension of prosecution for this case approved in the office communication of January 11, 2007 be terminated and prosecution resumed.

Remarks:

Claims 1-6, 8-14, and 17-24 are pending in this application. Claims 17-24 have been withdrawn. Claims 7, 15 and 16 were previously cancelled.

All of the pending claims are under rejection, as stated in the Advisory Action of December 22, 2006 (hereinafter, the Advisory Action). In summary, the pending rejections are:

Indefiniteness rejection of claim 1 under 35 U.S.C. § 112, ¶2 based on the phrase "one or more additional excipients";

New matter rejection of claims 1-6 and 17-24 under 35 U.S.C. § 112, ¶1;

Written description rejection of claims 1-6, 8-14, and 17-18 under 35 U.S.C. § 112, ¶1; and

Obviousness-type double patenting (provisional) of claims 1-6, 8-14, and 17-24.

35 U.S.C. § 112, ¶ 2: Claim 1

Applicants respectfully submit that the present amendment of claim 1, by which the phrase "one or more additional excipients" has been deleted, obviates this rejection. Claims 2, 3, 6, 13 and 14 have been amended to be consistent with claim 1 as amended.

35 U.S.C. § 112, ¶ 1: Claims 1-6 and 17-24

Paragraph 2 of the Advisory Action maintains a previous new matter rejection of claims 1-6 and 17-24 from the Final Office Action of June 29, 2006 (page 4). The Advisory Action states:

With regards to the new issue, on pages 2 and 6 of the specification as pointed out by Applicant does not contain a sterile aqueous solution with poloxamer 188 and one or more additional excipient stored under the conditions cited in the amended claims 1. (sic) Therefore the rejection is maintained.

-Advisory Action, p. 2.

Applicants understand this statement to indicate the Examiner's position that pages 2 and 6 of the specification do not disclose a sterile solution of propofol with Poloxamer 188 and one or more additional excipients and that the prior amendment explicitly referring to "additional excipients" therefore constituted the entry of new matter. Applicants again respectfully traverse this rejection. The addition of the reference to an "additional" excipient was coincidental with the limitation of claim 1, requiring the composition of that claim always to include Poloxamer 188. (See amendment of August 18, 2006). Poloxamer 188 is an excipient. (See, for example, specification page 14, line 28.) Accordingly, all other subsequent references to the inclusion of excipients in addition to Poloxamer 188 necessarily refer to additional excipients. Such compositions, including Poloxamer 188 and other excipients are seen for example in Example 6 on page 41. Example 6 describes the preparation of an exemplary sterile propofol composition comprising propofol and Poloxamer 188 (in addition to other components) as recited in claim 1. In addition, Example 8 discloses stability data for this composition that supports claim 1. See, in particular, Table 3 on page 43.

35 U.S.C. § 112, ¶ 1: Claims 1-6 and 8-14

Paragraph 3 of the Advisory Action maintains a previous written description rejection from the Final Office Action of June 29, 2006 (page 3). The Advisory Action states:

does NOT place the application in condition for allowance because: The rejection of 112-1 remain rejected especially with the term excipients for example in claim 1 as explained in the action of record. Addition of one or more excipients does not explain what constitutes these excipients. The rejection is maintained.

-Advisory Action, p. 2.

Applicants understand this statement to refer to and reiterate the written description requirement rejection in the final office action of June 29, 2006. Applicants respectfully submit that the claim amendments submitted herewith have also obviated this rejection. Claim 1 as amended no longer recites an open-ended recitation of excipients. Specifically, claim 1 as amended no longer recites "and one or more additional excipients." Furthermore, this rejection is inapplicable to claims 2, 3, 4, 6 and

14 because these claims do list specific excipients. For example, claim 2 now recites "one or more additional excipients selected from the group consisting essentially of" followed by a listing of suitable excipients.

Obviousness-type Double Patenting:

Finally, the Advisory Action maintains the previous obviousness-type double patenting rejection of claims 1-6, 8-14, and 17-24 which is provisional because the co-pending application, 10/629,308, has not yet issued. Applicants will address this rejection by filing a terminal disclaimer, if needed, when the claims have been deemed otherwise allowable, application 10/629,308 has issued or been allowed, and this rejection has been made final.

Conclusion

For the reasons stated above, applicants respectfully submit that the application as amended is in condition for allowance. A notice to this effect is respectfully requested. The Examiner is requested to telephone one of the applicants' undersigned representatives if any further issues stand in the way of a Notice of Allowance.

Respectfully submitted,

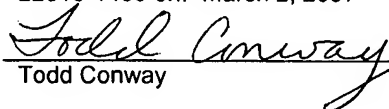



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The Director is hereby authorized to charge or credit Deposit Account No. 18-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith.

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